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10/562,866	05/16/2006	Bror Morein	72294-82303	6747

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EXAMINER

ARCHIE, NINA

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1645

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/562,866	Applicant(s) MOREIN ET AL	
	Examiner Nina A. Archie	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/29/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Drawings

2. The drawings in this application have been accepted. No further action by Applicant is required.

Specification

3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Information Disclosure Statement

4. The information disclosure statement filed on 12/29/2005 has been considered. An initialed copy is enclosed.

Election/Restrictions

5. Applicant's election with traverse of Group 1 claims 1-14 is acknowledged. According to PCT Rule 13.1 and 13.2. The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those

technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The traversal is on the ground(s) that Cox et al. does not disclose that fraction A of Quil A could be integrated alone in an iscom or iscom matrix particle and that fraction C could be free or that fraction C could be integrated in another different iscom particle or iscom matrix particle and mixed with the iscom or iscom matrix particle having fraction A of Quil A integrated therein. Cox et al. must comprise fraction A of Quil A and fraction C from Quil A in the same iscom particles or iscom matrix particles when iscoms are used. Also the species election is traversed in that the claims, and species, provide a single general inventive concept, that fraction A of Quil A could be integrated alone in an iscom or iscom matrix particle and that at least one other adjuvant could be in free form or could be integrated in another different iscom particle or iscom matrix particle and mixed with the iscom or iscom matrix particle having fraction A of Quil A integrated therein. Thus, Applicant respectfully requests withdrawal of the species election. Applicant believes that claims 1-14 read on the elected species.

This is not found persuasive. The lack of unity dated on 5/31/07 is based on the claims filed. The special technical feature of Group 1 is a method of enhancement of an immune response and immunomodulating activity comprising administration to a subject an effective amount of an adjuvant composition with synergistic effect, comprising: an iscom particle comprising a fraction A of Quil A; and together with at least one other adjuvant, in free form or integrated into another separate iscom particle. The Examiner interprets the claim as 1) an iscom particle comprising both a fraction A of Quil A and at least another adjuvant 2) an iscom particle comprising a fraction A of Quil A and a free form adjuvant separately 3) an iscom particle comprising a fraction A of Quil A and an adjuvant integrated into another separate iscom particle. Cox et al teaches a method of enhancement of an immune response and immunomodulating activity comprising administration to a subject an effective amount of an adjuvant composition with synergistic effect (see pg. 3 lines 20-30, pgs. 4-5). The method of Cox et al teach that an iscom matrix comprising a fraction of Quil A and can have at least one immunogen

(adjuvant), incorporated into or associated with the iscom matrix. Therefore the method of Cox et al teach a method of enhancement of an immune response and immunomodulating activity comprising administration to a subject an effective amount of an adjuvant composition with synergistic effect, comprising: an iscom particle comprising a fraction A of Quil A; and together with at least one other adjuvant, in free form or integrated into another separate iscom particle (see pg. 3 lines 20-30, pgs. 4-5). Therefore the species election is proper and unity is lacking.

The requirement is still deemed proper and is therefore made FINAL.

Applicant timely traversed the restriction (election) requirement in the response filed 9-4-07.

Claim Rejections - 35 USC § 102 and 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-2, 4-9, and 14 is rejected under 35 U.S.C. 102(b) as being anticipated by Friede et al US Patent No. 6,558,670 Date May 6, 2003.

Claims 1-2, 4-10, and 14 are drawn to a method of enhancement of an immune response and immunomodulating activity comprising administration to a subject an effective amount of an adjuvant composition with synergistic effect, comprising: an iscom particle comprising a fraction A of Quil A; and together with at least one other adjuvant, in free form or integrated into another separate iscom particle.

Friede et al teach a method of enhancement of an immune response and immunomodulating activity comprising administration to a subject an effective amount of an adjuvant composition with synergistic effect, comprising: an iscom particle comprising a fraction A of Quil A; and together with at least one other adjuvant (CpG) (see example 1). Fried et al teach that the CpG used in the adjuvant combinations of the present invention may be in free solution or may be complexed to ISCOMs. Friede et al teach that the CpG and saponin in the adjuvants or vaccines of the present invention may be separate or associated. Therefore the method of Fried et method of enhancement of an immune response and immunomodulating activity comprising administration to a subject an effective amount of an adjuvant composition with synergistic effect, comprising: an iscom particle comprising a fraction A of Quil A; and together with at least one other adjuvant, in free form or integrated into another

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separate iscom particle, wherein said at least one other adjuvant is integrated into one iscom particle, wherein said fraction A of Quil A is integrated into a first iscom particle and said at least one other adjuvant is integrated into a second iscom particle, wherein said at least one other adjuvant is integrated into a plurality of separate iscom particles (see "Detailed Description"). Friede et al teach that the haemolytic saponin preparations will further be combined with other adjuvants including Monophosphoryl Lipid A therefore the method of Fried et al teach the method according to claim 1 wherein said one other adjuvant is monophosphoryl lipid A and the method according to claim 7 wherein said at least one other adjuvant is at least one of Monophosphoryl Lipid A (see "Detailed Description"). Friede et al teach the method wherein said iscom particle is an iscom complex (Quil A, cholesterol, adjuvant), wherein in the composition further comprises a pharmaceutically acceptable carrier (see abstract).

7. Claims 1, 3-4, 9-10, and 14 is rejected under 35 U.S.C. 102(b) as being anticipated by Cox et al WO 96/11711 Date April 25, 1996.

Claims 1-2, 4-10, and 14 are drawn to a method of enhancement of an immune response and immunomodulating activity comprising administration to a subject an effective amount of an adjuvant composition with synergistic effect, comprising: an iscom particle comprising a fraction A of Quil A; and together with at least one other adjuvant, in free form or integrated into another separate iscom particle.

Cox et al teaches a method of enhancement of an immune response and immunomodulating activity comprising administration to a subject an effective amount of an adjuvant composition with synergistic effect (see pgs. 9-24). The method of Cox et al teach that an iscom matrix can have at least one immunogen (adjuvant), incorporated into or associated with the iscom matrix. Therefore the method of Cox et al teach a method of enhancement of an immune response and immunomodulating activity comprising administration to a subject an effective amount of an adjuvant composition with synergistic effect, comprising: an iscom particle comprising a fraction A of Quil A; and together with at least one other adjuvant, in free form or integrated into another separate iscom particle, wherein at least one other adjuvant is integrated into one iscom

particle (see pg. 3 lines 20-30, pgs. 4-5). Cox et al teach the method wherein the saponin fraction from Quil A is fraction B of Quil A, wherein said iscom particle is an iscom complex, wherein said iscom particle is an iscom matrix complex (see page 7 line 24).

8. Claims 1, 3, and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox et al. (WO96/11711).

Claims 1, 3, and 11-13 is drawn to a method according to claim 3, wherein the composition comprises 50-99.9% of fragment A of Quil A; and 0.1-50% of a fraction or derivative of Quil A based on the total weight of the composition, wherein the composition comprises 75-99.9% of fragment A of Quil A; and 0.1-25% of a fraction or derivative of Quil A based on the total weight of the composition, wherein the composition comprises 91-99.1% of fragment A of Quil A; and 0.1-9% of a fraction or derivative of Quil A based on the total weight of the composition.

Cox et al. teaches saponin preparation of saponins of *Quillaja saponaria* from 50 to 90% by weight of Fraction A and from 50 to 10% by weight of Fraction C, 50 to 70% by weight of fraction A and from 50 to 30% by weight of fraction C, about 70% by weight of fraction A, about 30% by weight of fraction C (claims 1-3), fractions A, B, and C (page 7, line 24). However, it does not teach the specific percentage weight claimed. The references also do not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454,456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the

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claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Status of the Claims

9. No claims are allowed.
Claims 1-14 are rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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A handwritten signature in cursive script, appearing to read "Nina Archie".

Nina A Archie

Examiner

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REM 3B31

A handwritten signature in cursive script, appearing to read "Mark Navarro".

MARK NAVARRO
PRIMARY EXAMINER